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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/502,066 | 10/27/2004 | W Wayne Lautt | 14233.18USWO | 8639 |

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MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

| EXAMINER | |
|---|---|
| GEMBEH, SHIRLEY V | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1614 | |

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/502,066 | LAUTT, W WAYNE | |
| | Examiner | Art Unit | |
| | Shirley V. Gembeh | 1614 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

Claims 1-42 are pending.

Claims 1-42 are rejected.

### *Response to Arguments*

The response filled 12/19/05 has been received and entered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Maintained Double Patenting*

On page 2 of Applicants' states application no. 10,350,478 has been abandoned. The petition to abandon that application was dismissed. The application is not abandoned.

Applicant's request that the Double Patenting rejection be held in abeyance is noted but no patentable subject matter can be indicated in the face of a standing ground of rejection.

### *Double Patenting-Statutory*

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 9, 14-19 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1,14, 17-19, 21 and 25 of copending Application No. 10/350,478. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The scope of the claims are the same, drawn to a method of reducing insulin resistance in a mammalian patient, administering a suitable acetylcholine esterase antagonist. The claims are directed to the same invention as that of claims in the co-pending of commonly assigned application 10/350,478, with publication number US 2003/0235609 A1 are word for word identical.

| Claim # | Current application 10/502,066 | Co-pending application 10/350,478 |
|---|---|---|
| 9 | 9. A pharmaceutical composition comprising a suitable acetylcholine esterase antagonist and at least one other drug used in the treatment of diabetes. | 19. A pharmaceutical composition comprising a suitable acetylcholine esterase antagonist and at least one other drug used in the treatment of diabetes. |
| 14 | 14. A kit comprising: an acetylcholine esterase antagonist in a pharmaceutically acceptable carrier; and instructions for the administration of the acetylcholine esterase antagonist to reduce insulin resistance in a mammalian | 17. A kit comprising: an acetylcholine esterase antagonist in a pharmaceutically acceptable carrier; and instructions for the administration of the acetylcholine esterase antagonist to reduce insulin resistance in a mammalian |

| | | |
|---|---|---|
| | patient. | patient. |
| 15 | 15. The kit of claim 14 further comprising means to administer the acetylcholine esterase antagonist. | 18. The kit of claim 17 further comprising means to administer the acetylcholine esterase antagonist. |
| 16 | 16. A method of reducing insulin resistance in a mammalian patient comprising administering a suitable acetylcholine esterase antagonist. | 1. A method of reducing insulin resistance in a mammalian patient comprising administering a suitable acetylcholine esterase antagonist. |
| 17 | 17. A method of amplifying the effect of the hepatic parasympathetic reflex on skeletal muscle insulin sensitivity comprising administering an acetylcholine esterase antagonist. | 14. A method of amplifying the effect of the hepatic parasympathetic reflex on skeletal muscle insulin sensitivity comprising administering an acetylcholine esterase antagonist. |
| 18 | 18. A method of increasing glucose uptake by skeletal muscle of a patient suffering from suboptimal hepatic regulation of blood glucose levels, comprising identifying the patient as suffering from suboptimal hepatic regulation of blood glucose levels and administering a suitable acetylcholine esterase antagonist. | 21. (ORIGINAL) A method of increasing glucose uptake by skeletal muscle of a patient suffering from suboptimal hepatic regulation of blood glucose levels, comprising identifying the patient as suffering from suboptimal hepatic regulation of blood glucose levels and administering a suitable acetylcholine esterase antagonist. |
| 19 | 19. A method of reducing insulin resistance in a mammalian patient suffering from inadequate levels of acetylcholine in the hepatic parasympathetic nerve synapses, said method comprising identifying the patient as suffering from inadequate levels of | 25. A method of reducing insulin resistance in a mammalian patient suffering from inadequate levels of acetylcholine in the hepatic parasympathetic nerve synapses, said method comprising identifying the patient as suffering from inadequate levels of |

| | | |
|---|---|---|
| | acetylcholine in the hepatic parasympathetic nerve synapses and administering a suitable acetylcholine esterase antagonist. | acetylcholine in the hepatic parasympathetic nerve synapses and administering a suitable acetylcholine esterase antagonist. |

The table sets forth the claims that are identical, i.e., word for word identical to the co-pending application. Applicant's commentary that the rejection is moot is noted but no patentable subject matter can be indicated in the face of a standing ground of rejection. The copending application is not abandoned due to the dismissed petition.

***Nonstatutory***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of copending Application No. 10/350,478 in view of Fischer, US. 2004/0209849 A1, Ponec, the New England Journal of Medicine Vol. 341 (3) pages 137-141(1999) and Lautt et al., US 5,561,165.

Although the conflicting claims are not identical, they are not patentably distinct from each other, because the claims of the instant application 10/502, 066 are to a composition, kit and a method of use, while the co-pending claims are drawn to a method of use and kit. However, the scope of use, using the same compound i.e., acetylcholine esterase antagonist in the manufacture of a medicament to reduce insulin resistance in a mammalian patient is the same.

Fischer, teaches known reversible inhibitors of acetyl choline esterase to be neostigmine, as in claim 15, at page 1 § 0007.

Ponec et al teach (page 141) neostigmine is metabolize by microsomal liver enzymes, hence, for example as in claim 10, a pharmaceutically acceptable liver targeting substance selected from the group of drugs listed in claim 11.

Lautt et al teach improving glucose tolerance (interpreted to be uptake of glucose) (claim 4) administering a cholinergic agonist in a mammal column 1 lines 35+, where the insulin resistance is at least partially the result of inadequate levels of

acetylcholine in the patient parasympathetic nerve synapses (see column 2 lines 45+, also column 5 line 1+), hepatic regulation of glucose levels is taught at column 3 line 12+.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the claims of the co-pending application 10/350,478 in view of Fischer, Ponec and Lautt et al.

The limitations of the instantly rejected claims are explicitly met by the prior art by combining the teachings of 2004/0209849 with that of Ponec and Lautt et al, administering a pharmaceutically acceptable liver targeting substance-acetylcholine esterase antagonist (neostigmine).

Thus the claims of the application are drawn to the same subject matter, an obvious variation of the co-pending application 10/350,478 claims it would have been obvious to one of ordinary skill in the art to combine the teachings of Fischer with that of Ponec and successfully achieved the claimed invention of the applicant at the time the invention was made. This is a provisional obviousness-type double patenting rejection.

Applicant's commentary that the rejection is moot is noted but no patentable subject matter can be indicated in the face of a standing ground of rejection. The copending application is not abandoned due to the dismissed petition.

No claims are allowed.

Note that Health professional data sheet indicates the site uptake for neostigmine is in the liver. (www.medsafe.gov.nz/Profs/Datasheet/n/Neostigmineinj.htm,)1996.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG
2/27/06

Christopher S. F. Low

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600